



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/880,576 | 06/13/2001 | Clifton A. Alferness | 11998.5USC2 | 7153 |

25764 7590 04/20/2006

FAEGRE & BENSON LLP
PATENT DOCKETING
2200 WELLS FARGO CENTER
MINNEAPOLIS, MN 55402

| |
|----------|
| EXAMINER |
|----------|

SZMAL, BRIAN SCOTT

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3736

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 09/880,576 | Applicant(s) ALFERNES ET AL. | |
| | Examiner Brian Szmal | Art Unit 3736 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18 and 32-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18 and 32-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2-9-06</u> . | 6) <input type="checkbox"/> Other: _____ |

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 18, 32, 34-37, 40 and 41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 17 of U.S. Patent No. 6,537,203 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current claims are written in a broader language than that of the issued claims. Furthermore, Claim 17 of '203 discloses the "step of pacing said heart", which would inherently disclose the use of an electrode structure as well as a pacing therapy.

3. Claims 18, 32, 34 and 36-41 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 30, 40 and 41 of U.S. Patent No. 6,564,094 B2. Although the conflicting claims are not identical, they

Art Unit: 3736

are not patentably distinct from each other because the current claims are written in a broader language than that of the issued claims.

4. Claims 33 and 35 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 25, 30, 40 and 41 of U.S. Patent No. 6,564,094 B2 in view of Alferness et al (6,567,699 B2). Alferness et al ('094) fails to claim the use of sutures to secure the device to the heart, as well as the jacket material is substantially a non-elastic material. Alferness et al ('699) discloses the use of sutures to secure the device to the heart as well as the use of a non-elastic material for the jacket. Since both Alferness et al ('094) and Alferness et al ('699) disclose heart jackets that apply an electrical therapy to the heart, it would have been obvious to one of ordinary skill in the art to claim the use of sutures and a non-elastic material, as per the teachings of Alferness et al ('699), due to the previous disclosures of such limitations.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 18, 32 and 34-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilk (5,533,958).

Wilk discloses a heart assist method and further discloses accessing the heart; selecting a device to be placed on the heart; placing the device on the heart, the device

Art Unit: 3736

comprising a biocompatible material configured to engage a surface of the heart to constrain circumferential expansion of the heart; passing an electrical current to the heart with the current to apply an electrical therapy to the heart; securing the device on the heart; adjusting the device to snugly conform to the external geometry of the heart; the biocompatible material is a non-elastic material; passing an electrical current to the heart is accomplished using electrical elements; the electrical elements are pacer leads; an electrical current is passed from the heart; defibrillating therapy; pacing therapy; and the device is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume. See Figures 8 and 9; Column 5, lines 61-67; Column 6, lines 1-7 and 19-39; and Column 7, lines 1-9.

Response to Arguments

7. Applicant's arguments, filed February 7, 2006, with respect to the rejection(s) of claim(s) 18 and 32-37 under Kung et al (6,508,756 B1) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Wilk (5,533,958).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone


Art Unit: 3736

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



BS



MAX F. HINDENBURG
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700